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Can genetic engineering for the poor pay off? An ex-ante evaluation of Golden Rice in India

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Discussion papers in this series are intended to stimulate discussion among researchers, practitioners and policy makers. The papers mostly reflect work in progress. This paper has been reviewed by J.V. Meenakshi (HarvestPlus, Washington, DC), whom we thank for her valuable and pertinent comments. Shorter and partially incomplete drafts have been reviewed by Ingo Potrykus (Prof. em., Swiss Federal Institute of Technology, Zürich), Peter Beyer (Univ. of Freiburg), Gerard Barry (International Rice Research Institute, Los Baños), Umesh Kapil (All India Institute of Medical Sciences, New Delhi), Adrian Dubock (Syngenta International, Basel), and Ira Matuschke (Univ. of Hohenheim, Stuttgart).

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Abbreviations and Acronyms

μg/g	-	microgram per gram
CGIAR	-	Consultative Group on International Agricultural Research
DALY	-	disability-adjusted life year
GE	-	genetic engineering
GM	-	genetically modified
GMO	-	genetically modified organism
ICDS	-	Integrated Child Development Services
IDA	-	iron deficiency anaemia
PDS	-	Public Distribution System
R&D	-	research and development
RDA	-	recommended dietary allowance
Rs.	-	Indian Rupees (Rs. 43 ≈ 1 US$)
VA	-	vitamin A
VAD	-	vitamin A deficiency
w/o	-	without

Abstract

Genetic engineering (GE) in agriculture is a controversial topic in science and society at large. While some oppose genetically modified crops as proxy of an agricultural system they consider unsustainable and inequitable, the question remains whether GE can benefit the poor within the existing system and what needs to be done to deliver these benefits? *Golden Rice* has been genetically engineered to produce provitamin A. The technology is still in the testing phase, but, once released, it is expected to address one consequence of poverty – vitamin A deficiency (VAD) – and its health implications. Current interventions to combat VAD rely mainly on pharmaceutical supplementation, which is costly in the long run and only partially successful.

We develop a methodology for ex-ante evaluation, taking into account the whole sequence of effects between the cultivation of the crop and its ultimate health impacts. In doing so we build on a comprehensive, nationally representative data set of household food consumption in India. Using a refined disability-adjusted life year (DALY) framework and detailed health data, this study shows for India that under optimistic assumptions this country's annual burden of VAD of 2.3 million DALYs lost can be reduced by 59.4% hence 1.4 million healthy life years could be saved each year if Golden Rice would be consumed widely. In a low impact scenario, where Golden Rice is consumed less frequently and produces less provitamin A, the burden of VAD could be reduced by 8.8%. However, in both scenarios the cost per DALY saved through Golden Rice (US$3.06-19.40) is lower than the cost of current supplementation efforts, and it outperforms international cost-effectiveness thresholds. Golden Rice should therefore be considered seriously as a complementary intervention to fight VAD in rice-eating populations in the medium term.

Keywords: genetic engineering, beta-carotene biofortification, vitamin A deficiency, Golden Rice, health benefits, DALYs, cost-effectiveness, cost-benefit analysis, India.

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1 Introduction

One controversial and long-running topic in science, politics and society is genetic engineering (GE) in agriculture. Since the introduction of the first genetically modified (GM) food crop into the market, i.e. since the introduction of the “Flavr Savr” tomato in 1994 (FDA 1994, USDA 1994), and even more so since the more successful commercial cultivation of subsequent GM crops from 1996 onwards (James 2004), public opinion about genetically modified organisms (GMOs) has been deeply divided. In the context of developing countries, there are generally four arguments in favour of GM crops (Figure 1) namely that they have the *potential* to:

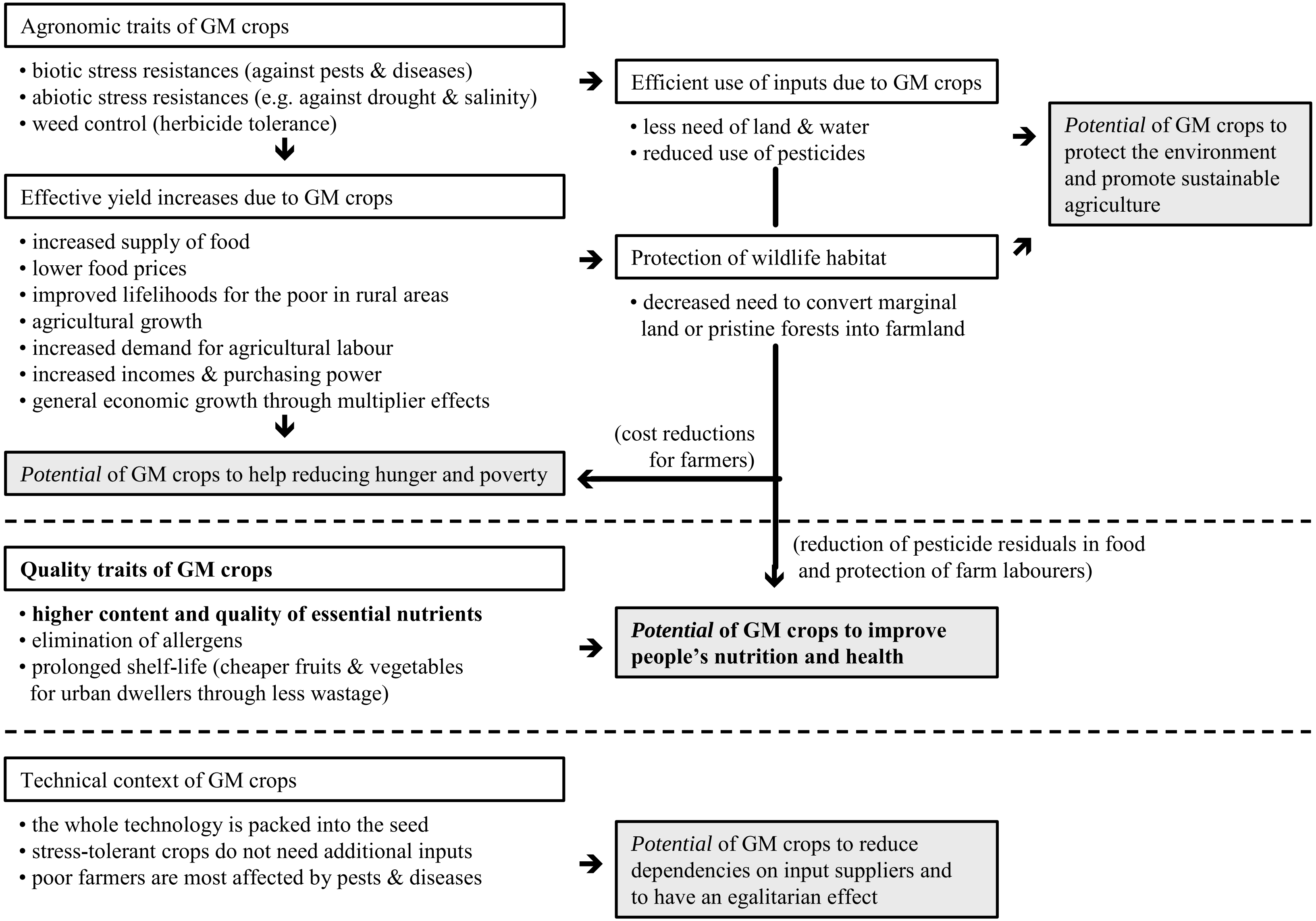
- increase effective yields and contribute to the fight against hunger and poverty,
- promote sustainable agriculture and help to reduce environmental degradation,
- have a positive impact on people’s nutrition and health,
- strengthen the position of poor and small-scale farmers.

On the other hand GMOs are – sometimes diametrically – criticised for their *potential* to:

- threaten human and animal health (i) through toxins or allergens in GM crops, (ii) through the build-up of antibiotic resistances or (iii) through as of yet unknown risks,
- erode biodiversity and threaten the ecosystem through vertical or horizontal gene flow,
- create new problems in agriculture (i) through the build-up of resistances or (ii) through the appearance of “super weeds” through gene flow,
- generate a predominant position of multinationals in agricultural markets and create new dependencies of both poor farmers and poor countries in the seed and food supply,
- overstrain the technical and financial capacities of both small-scale farmers to safely manage GM crops and developing countries at large to develop biosafety regulations,
- simplify the issue of hunger and poverty and detract from other strategies,
- lead to neglecting the genuine needs of small-scale farmers like access to means of production, education and markets, etc.,
- endanger export markets and the markets of organic farmers, if buyers reject GMOs,
- neglect the sovereignty of poor countries and the freedom of choice of poor farmers and consumers in developing countries.

To reproduce this discussion in any detail is certainly beyond the scope of this paper, but more comprehensive discussions and different points of views are, e.g., represented in Conko & Prakash (2004), FYF (2002), Nuffield Council (2003), Orton (2003), Pew Initiative (2004), Qaim (2001), Raven (2004), Sahai (2004) and Timmer (2003). Yet, while there is regulation to ensure that potential risks of GMOs do not materialise, adequate steps might also need to be undertaken to ensure that desired benefits of GMOs, especially in the context of developing countries, come about.

Figure 1: Potential benefits of GM food crops and their underlying rationale



To shed light on the terms under which one often vented benefit of GM crops – the potential contribution of GE to the alleviation of malnutrition through the improvement of the nutritional contents of staple crops – can materialise in a viable manner is the objective of the present study. The prime example for this approach is popularly known as *Golden Rice*, a rice strain that is – by means of genetic engineering – biofortified with beta-carotene and other carotenoids, which the human body can convert into vitamin A (Beyer et al. 2002).[1] While Golden Rice has been under attack of activists, not only for being a GMO but also for being a supposed hoax regarding its original purpose of improving the vitamin A (VA) status of at-risk populations (see appendix 2, Shiva 2000, Greenpeace 2001a-2005),[2] scientific studies have indicated that Golden Rice, especially if its beta-carotene content would be increased, *can* indeed contribute – in a cost-effective manner – to the alleviation of vitamin A deficiency (VAD), save children's eye-sights and lives, provide considerable welfare gains and boost the productivity of unskilled workers (Zimmermann and Qaim 2004, Anderson et al. 2004, Dawe et al. 2002). The importance of choosing rice as a vehicle for fortification in general has, for instance, been stated by Dexter (1998).

Since these analyses were undertaken, the development of Golden Rice has taken a great leap forward, by now showing beta-carotene levels of up to 20 times those of the first lines (Paine et al. 2005). Moreover, in the framework of HarvestPlus, the micronutrient Challenge Programme of the Consultative Group on International Agricultural Research (CGIAR), a model to analyse the costs and benefits of biofortified crops has been developed to allow a consistent and more rigorous economic evaluation of food crops rich in beta-carotene, iron and zinc (Stein et al. 2005a). And in the meantime, germplasm of Golden Rice has also been transferred to India, where the country-specific adaptation of Golden Rice to a selection of local varieties is currently taking place.

Given the continuing controversy surrounding Golden Rice, the new, standardised framework for analysing biofortified crops and the new factual situation, a renewed look at the potential benefit of Golden Rice is warranted to update its evaluation from a scientific point of view and to investigate the economic rationale for its further development and future dissemination. This is the more important as, in her review of food-based approaches, Ruel (2001) found that studies analysing the cost-effectiveness of these interventions – amongst which she also counts "plant breeding strategies" – are absent from the literature, wherefore she underlines the need to close this gap.

In addition, for India a large-scale and nationally representative household survey is available, which includes detailed and disaggregated information on the households' food consumption (NSSO 2000), and which is complemented by expert interviews (Ategbo 2005, Barry 2005, Dubock 2005, Kapil 2005, Laviolette and Bulusu 2005, Mayer 2005, Ramachandran 2005, Rao 2005, Singh 2005, Sinha 2005). Using such a data set allows deriving the current consumption of beta-carotene and VA at an individual level (through the use of adult equivalent weights that can be generated from within the data set) and, hence, the data set allows simulating the impact of Golden Rice on the "intake gap" of the representative individuals in the sample. Results obtained this way are superior to results of calculations that are based on simple national average

[1] Those carotenoids that the human body can convert into VA are also subsumed under the term "provitamin A" (NIH 2005), which is why these terms are used somewhat interchangeably in the following. In turn, VA is also called "retinol".

[2] For a reply see Conway (2001). A more differentiated view can be found in MASIPAG (2001), where the main criticism is put on the very agricultural system in which Golden Rice is propagated (i.e. technology-oriented monoculture that is dominated by oligopolistic suppliers in "the North"). Of course this view explains much of the controversy around Golden Rice and GM crops in general: while these crops can be assessed favourably from within the system, they are only part of the problem if the system itself is assessed in a negative way and if the solution is seen in a system change.

consumption data – as those by Zimmermann and Qaim (2004). Indeed, according to Murphy and Poos (2002), average intakes cannot be used to assess the nutrient adequacy of group diets because the prevalence of inadequacy depends on the shape and variation of the intake distribution. Using this data set and applying the aforementioned new framework to analyses of iron-rich and zinc-rich rice and wheat in India have shown the potential of biofortification through conventional breeding to reduce the overall burden of the respective deficiencies in a cost-effective manner (Stein et al. 2005b and forthcoming). The present study seeks to answer the question whether biofortifying staple crops through GE can be cost-effective, too. That is, can genetic engineering for the poor pay off?

In the following, section 2 presents the methodology used to determine the burden of VAD in India and reports the result. Section 3 describes micronutrient interventions in general and what is currently being done in India to combat VAD. Section 4 explains the data and the assumptions used for computing the impact of Golden Rice on the burden of VAD and reports the result. Section 5 puts the effect of Golden Rice in relation to its cost and analyses the result in comparison to alternatives and different "yardsticks". Section 6 concludes. In the appendix a cost-benefit analysis of Golden Rice is carried out.

2 The burden of vitamin A deficiency in India

Toteja and Singh (2004) have done a comprehensive survey of studies and data on VAD in India. According to their "micronutrient profile", no data is available on the prevalence of VAD at a national level, but data of the late 1990s indicates state-wise prevalence rates of Bitot's spot amongst preschool children in the range of 0-3 percent, with an average of 0.7 percent;[3] Toteja and Singh point out that these prevalence rates have experienced a considerable decline from about 4 percent in 1980, rendering clinical VAD a more "local and focal" problem. With regard to night blindness amongst pregnant women Toteja and Singh quote studies that show prevalence rates for different states in the range of 0.59-23.9 percent. For sub-clinical VAD they simply state that the available information on serum retinol levels indicates very high levels of VAD and for the intake of VA they report that in most parts of the country the average intake is about 50 percent of the recommended dietary allowance (RDA). In the 10th Five Year Plan of the Planning Commission of the Government of India (GoI 2002) it is likewise stated that the intake of VA amongst young children, adolescent girls and pregnant women is significantly below their respective RDAs. According to the 10th Five Year Plan, the prevalence of VAD signs amongst pregnant and lactating women ranges from 1 to 5 percent, with large variation between and within states. The Five Year Plan also indicates, that sub-clinical VAD "might perhaps" be more widespread.

According to Stein et al. (2005a) it is not so much an abstract prevalence rate of VAD *per se* that is of interest but rather the related adverse functional health outcomes, as those are the actual problems that cause the burden of VAD. In this context, sub-clinical levels of VAD and the prevalence of Bitot's spot are not considered to be relevant, as there is no scientifically proven link to any direct impact on people's health and well-being; VAD-related health outcomes that are common and that do have a proven adverse effect are night blindness, corneal scars, blindness, measles and increased mortality amongst children and night blindness amongst pregnant and lactating women. In this assessment of the health outcomes of VAD Stein et al. (2005) differ somewhat from Zimmerman and Qaim (2004). Yet, while the latter are agricultural economists, Stein et al.'s handbook was co-authored by eminent nutritionists and physicians who took care to stick to what is scientific consensus regarding VAD and the related health outcomes. While consideration of consensual consequences of VAD only should ensure broad acceptance

[3] Bitot's spot is a disease of the eye that is caused by VAD and whose prevalence is sometimes used as proxy for the prevalence of VAD.

of the results, it nevertheless risks omitting outcomes of VAD for whose causality there is no clear-cut scientific proof yet. Therefore any assessment of VAD based on this limited number of health outcomes also risks underestimating the true burden of VAD.

To measure the burden of VAD across these different health outcomes and target groups Stein et al. (2005b) have developed a framework based on "disability-adjusted life years" (DALYs), which builds on prior work by Zimmermann and Qaim (2004) and the original work by Murray and Lopez (1996). The present study is the first in-depth application of this model. DALYs enable combining morbidity information with mortality figures by weighting diseases according to their respective severity (Table 1). These disability weights, together with information on incidence and mortality rates and the duration of each condition, then enter the following formula that yields the number of DALYs that are lost every year due to VAD:

$$DALYs_{lost} = \sum_j T_j M_j \left(\frac{1-e^{-rL_j}}{r} \right) + \sum_i \sum_j T_j I_{ij} D_{ij} \left(\frac{1-e^{-rd_{ij}}}{r} \right)$$

Where T_j is the total number of people in target group j, M_j is the mortality rate associated with the deficiency in target group j, L_j is the average remaining life expectancy for target group j, I_{ij} is the incidence rate of disease i in target group j[4], D_{ij} is the disability weight for disease i in target group j, d_{ij} is the duration of the disease i in target group j (for permanent diseases d_{ij} equals the average remaining life expectancy L_j), and r is the discount rate for future life years (set at 3 percent).

Table 1: Severity, duration and incidence rates of VAD-related diseases

	Night blindness	Corneal scars	Blindness	Measles w/o complications	Measles with complications
			Children ≤ 5 [a]		
Disability weight	0.05	0.2	0.5	0.35	0.7
Duration	1 year	rest of life	rest of life [b]	10 days	20 days
Prevalence rate	1.03%	0.12%	0.12%	N/A	N/A
Incidence rate	N/A [c]	N/A [c]	N/A [c]	2.7% [d]	2.7% [d]
			Pregnant & lactating women		
Disability weight	0.1	N/A (not applicable)			
Duration	5 & 6 months				
Prevalence rate	2.76% [c]				

Source: Stein et al. (2005a), incidence and prevalence rates are based on Toteja et al. (2001). [a] For night blindness the target group is children aged 1-6 years. [b] Blindness is assumed to be preceded by a bout of corneal scars of 1.5 years. [c] For night blindness, corneal scars and blindness health statistics usually only contain data on prevalence rates. However, these rates can be converted into incidence rates (Stein et al. 2005a). [d] For measles a higher incidence rate is assumed than the one that is given in the official data of the Central Bureau of Health Intelligence (CBHI) because for some states no data is available and it is known that there is substantial under-reporting of the morbidities reported therein.

Based on these assumptions, the burden of VAD in India amounts to 2.3 million DALYs lost each year, of which 2 million DALYs are lost due to mortality and 286,000 DALYs are lost due

[4] For a discussion of the possibilities to transform prevalence rates ("stock") that are often given in health statistics into incidence rates ("flow") that are needed for the DALY formula see Stein et al. (2005b).

to morbidity. Compared to the 4.0 million DALYs that are lost each year due to iron deficiency anaemia (IDA) in India (Stein et al. 2005b), VAD is a smaller problem. However, while for IDA these 4.0 million DALYs arise from 22.5 million new people that are affected by IDA each year, the 2.3 million DALYs lost due to VAD are lost by only 3.9 million new people who are affected by VAD each year (Table 2). Consequently each new case of IDA causes on average a loss of 0.18 DALYs, while each new case of VAD causes an average loss of 0.60 DALYs. Hence IDA affects more people but VAD has more severe health consequences. In any case, an annual loss of 2.3 million healthy life years through VAD justifies interventions to combat it, which will be discussed in the following section. It also warrants a thorough evaluation of potential alternative and complementary approaches to reduce this burden on the Indian society, which is the purpose of this analysis of Golden Rice.

Table 2: Width and depth of VAD and IDA in India

Functional outcome	Target group	New cases per year (problem width)	DALYs lost per year (problem depth)
	children 1-6	1,595,201	78,576
Night blindness	pregnant women	1,028,001	76,239
	lactating women	381,781	37,611
Corneal scars [a]	children ≤ 5	3,663	20,876
Transitory corneal scars [a]	children ≤ 5	3,663	1,074
Blindness [a]	children ≤ 5	3,663	52,190
Measles	children ≤ 5	411,971	3,949
Severe measles	children ≤ 5	411,971	15,789
Mortality	children ≤ 5	71,625	2,041,145
Sum for VAD-related health outcomes		3,911,539	2,327,448
Sum for IDA-related health outcomes		22,593,114	4,031,474

Source: Own calculations. For background on IDA calculations see Stein et al. (2005b). [a] Of all VAD-related cases of corneal scars 50 percent are assumed to lead to blindness, after a transitory phase of 1.5 years; this is why the number of new cases is the same for each condition. The related numbers of DALYs lost are vastly different, though, because in the case of "just" corneal scars the future losses of good health are added up and discounted over the remaining live expectancy, whereas for transitory corneal scars the losses are only added up over 1.5 years; the future losses of good health due to blindness are also added up and discounted over the remaining live expectancy, but the disability weight for blindness is higher than for corneal scars, which is why the number of DALYs lost is also higher.

3 Interventions to combat vitamin A deficiency

3.1 Current methods to combat micronutrient deficiencies

In general, five different interventions to combat VAD can be differentiated: pharmaceutical supplementation, industrial fortification,[5] biofortification, dietary diversification and supporting

[5] Industrial fortification is also described as "commercial fortification" to differentiate it from home-based fortification or from food-to-food fortification; however, this term is imprecise as industrial fortification can be mandatory, hence it is not necessarily "commercial". With the appearance of biofortification it has, moreover, become necessary to differentiate further between the different fortification approaches. For this purpose the adjective "industrial" describes where the fortification takes place, namely at the stage of food processing once the crops have

public health measures. In the following the particular strengths and weaknesses of each of these general micronutrient interventions will shortly be discussed (for the underlying, more detailed discussions see Kennedy et al. 2003, Bulusu 2000, Bouis 2002a and 2002b, Underwood 1999, Allen 2003, Jasti et al. 2003, Ruel 2001, and Clugston and Smith 2002).

3.2 Pharmaceutical supplementation

Supplements are an effective, technical approach to deliver high doses of micronutrients and, thus, to convey an adequate level of protection against micronutrient deficiencies within a short term. Yet, supplements do not tackle the root of dietary deficiencies, which is inadequate and poor quality food. And if broader groups of society are deficient, or if the supplementation programme is to cover hard-to-reach target groups, or if it is to achieve universal coverage, the financial, administrative and human resources needed become substantial, overshadowing the costs of the capsules by far and making this approach increasingly inefficient, less sustainable over the long-run and susceptible to budget cuts. There is also the issue of acceptance of the supplements by the target groups and, in the case of supplements that need to be taken more frequently, compliance of the potential beneficiaries can become an issue.

3.3 Industrial fortification

The rationale of industrial fortification is to enrich food that is eaten widely by populations at risk of micronutrient malnutrition with appropriate amounts of the micronutrient needed. In places and situations where there are suitable food vehicles and fortificants, centralised processing facilities, efficient food distribution and marketing channels and no procurement constraints of those in need due to lack of purchasing power, this is an easy, rather cost-effective and straight-forward approach. Yet, except for iodised salt, this is generally not seen to be the case in those developing countries where micronutrient deficiencies pose a public health problem: not all foods are suitable vehicles and those that are, are often not consumed by the (rural) poor. In the case of VA cooking oil could be a promising candidate, though.

3.4 Biofortification

Like industrial fortification, biofortification efforts have the objective to increase the micronutrient content in the food that is eaten by deficient populations. Only in this case this is not done during food processing but through breeding of micronutrient-rich crops. Hence, unlike with industrial fortification, there are lower monitoring costs and no recurrent costs for buying the fortificant; there is only one big initial investment in the development of a biofortified staple crop, which can then be adapted and used in countries around the world. This makes biofortification very cost-effective. Moreover, once farmers grow the biofortified crops, these crops will reach at-risk populations even if resources and public attention shift away from the problem. Contrary to industrially fortified food – which requires central processing facilities and only reaches consumers who can afford to buy processed food – biofortified crops already contain higher levels of micronutrients in their raw form and, thus, also reach those people who consume their own produce, who live in remote areas with poor access to the marketing channels of processed food or who simply cannot afford industrially fortified foodstuff. In the case of beta-carotene fortification another advantage is that the risk of overdosing is not an issue because the human body only converts as much beta-carotene into VA as it needs.[6] A drawback of beta-carotene is its higher instability when stored or exposed to light and heat.

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left the farm; whereas the "bio" in biofortification indicates that the micronutrient enrichment takes place on the farmers' fields within the plant itself.

[6] But also biannual supplementation with mega doses of VA only carries a theoretical risk of overdosing (if the programme were to be poorly implemented and executed, c.f. footnote 7).

3.5 Dietary diversification and behaviour change

Dietary diversification aims at increasing the intake of foods high in micronutrients, like green leafy vegetables, orange-fleshed fruits and tubers, citrus fruits and animal source foods. This can either be achieved through increasing the (own) production, processing, and marketing of such food or through nutrition education that aims at changing cooking methods and eating behaviour; the latter also contributes to consumer sovereignty and self-determination. Dietary diversification is generally considered the most desirable and sustainable solution in the long run, because it improves overall dietary quality instead of addressing single micronutrient deficiencies only.

3.6 General public health measures

Public health measures that may back micronutrient interventions and reduce underlying causes of malnutrition (and which also improve the overall standard of living) are, for instance, provision of clean drinking water, improvements of personal hygiene, de-worming and better access to health-care services.

These interventions can be ranked according to their effectiveness (i.e. the level of immediate protection they can provide) and according to their sustainability (i.e. their desirability in the long run) – and these two possibilities yield opposite results (Figure 2). Yet, each intervention has its strengths and weaknesses, and it is commonly understood that integrated and combined strategies are needed to address the issue of micronutrient malnutrition (e.g. Kennedy et al. 2003, Bouis 2002b)

Figure 2: Effectiveness vs. sustainability of VAD interventions

High	← **Effectiveness**	←	*Low*	
Pharmaceutical supplementation	Industrial fortification	Biofortification	Food diversi-fication	Public health measures (supportive role)
Low	→ **Sustainability**	→	*High*	

Source: Own representation.

3.7 Current interventions to combat vitamin A deficiency in India

The main current intervention to combat VAD in India is supplementation: there is a national programme that addresses VAD amongst children aged 9 to 36 months (Toteja and Singh 2004). This supplementation programme, the National Prophylaxis Programme Against Nutritional Blindness, was initiated in 1970. Yet, while the 10th Five Year Plan claims that earlier bottlenecks like lack of infrastructure and adequate supplies have been corrected, it concedes that coverage levels are still very low and that during the preceding ninth plan no substantial improvement of the programme's coverage level has taken place (GoI 2002). In some states the Micronutrient Initiative (MI), supported by UNICEF, provides additional supplementation to cover children aged 3 to 6 years, which are not a target group of the government programme. MI and UNICEF also support the government programme to compensate shortfalls in supply and to improve monitoring (Laviolette and Bulusu 2005, Ategbo 2005). MI (2004) states in its annual report that only about 40 million children in India under 5 years of age are adequately covered by the ongoing supplementation efforts and according to UNICEF (2004) only 25 percent of children in India aged 6 to 59 months have received at least one high dose of VA in 2001. This latter figure is even below the result of the National Family Health Survey (NFHS-2) 1998-99, which found a coverage rate of 29.7 percent of children aged 12 to 35 months who received at least one dose of VA, of which only 17 percent received a dose within the last six months prior to the survey. The NFHS-2 concludes that "this indicates that a large majority of children in India have not received vitamin A supplementation at all and even fewer children receive vitamin A supplementation regularly" (IIPS 2000, p. 213).

Apart from infrastructure and supply bottlenecks, Arora et al. (2002) found that health providers accorded less importance to VAD than to IDA and were rather passive in the implementation of the programme. This was accompanied by a lack of conceptual clarity regarding the programme components, its target groups and the correct administration of the supplements. As the most important reason for the non-utilisation of the programme's services they specified unawareness and inadequate social mobilisation. Yet, the universal and indiscriminate distribution of high dose supplements also has its detractors, who point to regional differences in the prevalence of VAD and question the usefulness of supplementations campaigns in general (Kapil et al 2004, Kapil 2002, Desai 2002).[7] Other current VA interventions are the mandatory fortification of "vanaspati" (shortening made of hydrogenated vegetable oil), and the fortification of milk in some locations (Chakravarty 2000).[8]

Given this background, experts that were interviewed were open but cautious regarding Golden Rice as a complementary approach of enriching a widely eaten staple food with beta-carotene (Laviolette and Bulsu 2005, Ategbo 2005, Kapil 2005, Sinha 2005, Ramachandran 2005). The general attitude seemed to be to support Golden Rice once it is regulated by the Indian authorities, once its effectiveness and practicability in reaching the target population and in providing them with a sufficient protection against VAD is proven, and once it is shown that Golden Rice is more cost-effective than supplementation and does not impact negatively on local agriculture. In parts there is also some willingness to embrace Golden Rice because it is a food-based approach that could help to break the dependency on an oligopolistic global market where only a few multinationals provide synthetic VA and VA precursors that are needed for the national supplementation programme (Kapil cited in Desai (2002) and in Mudur (2001)).[9]

In other parts the over-arching importance of dietary diversification and nutrition education to address such an intricate problem as micronutrient malnutrition was underlined and the potential contribution of Golden Rice was put in perspective. Though this was seen as an important and potentially limiting factor to varying degrees, the issue of acceptability of yellow rice did not seem to be considered an insurmountable obstacle. At this point in time and given the focus as well as the scope of this study, this assessment necessarily remains a hypothesis; an in-depth analysis of future consumer behaviour towards Golden Rice and the acceptability of its colour continues to be an open research question.

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[7] Poor or unnecessary execution of VA supplementation has even been held responsible for causing the death of children through overdosing (Mudur 2001, Kapil 2004, Bhaumik 2003, Solomons and Schümann 2004). Yet, in this occasion, media coverage and a related wave of hysteria might have had a role in determining the perception of the incident (West and Sommer 2002, Reddy 2002). Nevertheless, one ethically correct approach to combat both VAD *and* prevent overdosing has been proposed by Solomons and Schümann (2002), namely to rely on fortification or to use innocuous provitamin A carotenoids – two suggestions that are combined in Golden Rice.

[8] However, vanaspati only has to be fortified with VA to a level of 4 percent of RDA and Chakravarty (2000) questions its effectiveness because the rural population consumes very little vanaspati (she gives the figures of 0.3-1.1 grams/day); she also points out that VA may be destroyed on repeated heating. Chakravarty (2000) also questions the general effectiveness of the fortification of milk because of the low consumption of milk among lower socio-economic strata.

[9] Indeed, in the 1990s there was a global "vitamin cartel" (Marshall 2005) and companies producing VA (foremost amongst them Hoffman-La Roche) were charged for collusion and price fixing in the EU, the USA, Canada and Australia (Guardian 2001, EU 2001, Joshua and Zane 2001). Iyer (1999) reports how India's only major producer of VA is dependent on Hoffman-La Roche as a supplier of preliminary products.

4 Golden Rice in India

4.1 Scenarios for an *ex-ante* analysis

Golden Rice is not yet out in farmers' fields or on consumers' plates, this study therefore necessarily takes an *ex-ante* approach. While some parameters for the analysis can already be ascertained, others need to be estimated. To take account of the uncertainty surrounding such estimates and assumptions, we use two scenarios, a high impact one and a low impact one, to cover the range of potential results.

4.2 Data and assumptions about Golden Rice

The amount of carotenoids in the first strains of Golden Rice was 1.6 μg/g (Ye et al. 2000). Since then the beta-carotene content in Golden Rice rose consistently, up to 31 μg/g according to the latest developments (Paine et al. 2005).[10] In this study this value will be used to illustrate the potential impact of Golden Rice in a high impact scenario. For the low impact scenario we will use a beta-carotene content of 14 μg/g, which corresponds to the average content of beta-carotene in the 23 events reported in Paine et al. (2005). According to Mayer (2005) and Singh (2005) this new strain of Golden Rice will be made available to Indian researchers by the end of 2005 in the context of the humanitarian free licences that owners of relevant intellectual property rights have granted for Golden Rice (Potrykus 2001). The post-harvest losses to the beta-carotene content in Golden Rice (due to storage, processing and cooking) are expected to range from 35 to 80 percent (Barry 2005, Dubock and Beyer 2005). While for beta-carotene in a mixed diet a rate of 12:1 is used (IOM 2002), better rates for Golden Rice are justified due to its simple food matrix, as already discussed elsewhere (Zimmermann and Qaim 2004) and as confirmed by Russell (2006). Therefore a conversion factor of 6:1 is used to convert micrograms of beta-carotene into micrograms of VA when computing VA intakes for the low impact scenario. In the high impact scenario we assume a conversion rate of 3:1. These conversion rates include both the absorption of beta-carotene through the human body and its conversion into VA.

4.3 Data and assumptions about vitamin A consumption in India

To establish the potential impact of Golden Rice, a representative national survey of about 120,000 households was used that recorded the consumption of over 140 different food items (NSSO 2000). Within these different food items also the consumption of "rice - P.D.S.", "102 rice - other sources", "chira", "khoi, lawa", "muri" and "other rice products" was recorded separately.[11] This enables analysing the impact of Golden Rice at a very disaggregated level, in particular differentiating between rice that was purchased through the Public Distribution System (PDS) and other rice. To derive the current consumption of VA, national food composition values were applied to the survey's unit record data, supplemented by the nutrient database of the U.S. Department of Agriculture and by the Sight and Life Vitamin A intake calculator where necessary (Gopalan et al. 1989, USDA 2004, Erhardt 2005). Beta-carotene intakes were converted into VA by using a conversion factor of 12:1. Individual intakes were derived by means of adult equivalents, i.e. the survey data on household composition, expressed in age and gender groups, was used to compute the relative weight of each group in overall VA consumption. In a second step, the future intakes of VA with Golden Rice in the two scenarios was simulated by adjusting the food composition value for part of the rice consumed when deriving the VA intake from the survey data, i.e. in these simulations beta-carotene contents of 14 and 31 μg/g were used instead of 0 μg/g. In using such detailed consumption data at the individual level, we improve on the study by Zimmermann and Qaim (2004) who use a simple shift in *mean* national

[10] The total carotenoid content in this strain is 36.7 μg/g, but carotenoids other than beta-carotene only play a minor role in the metabolism of VA and are therefore disregarded.

[11] These are the terms used on the questionnaire "Household Schedule 1.0" (NSSO 2000).

intakes to approximate the behaviour of intakes at the lower end of the underlying intake *distribution* curve (i.e. on the part of the population suffering from VAD).

4.4 Data and assumptions about the spread of Golden Rice in India

One key determinant of the potential effectiveness of Golden Rice is, of course, the share it reaches in the consumption of rice of populations with low VA intakes. Unlike iron-rich rice, where no changes to either the agronomic or the consumer characteristics of the rice are expected, the micronutrient density of Golden Rice is easily recognisable through its yellow colour. In this case the micronutrient trait cannot only be bundled with other desirable traits like higher yields or better disease resistance, which allows it to piggy-back on these traits and to rely to a greater extent on this supply-driven push for its adoption by farmers and its subsequent spreading through the food chain. (This does not mean that for mineral-dense staple crops supporting social marketing will be unnecessary to inform and educate consumers.) Therefore, in addition to agronomic superiority, also demand-driven pull factors can be expected to play an important role in achieving the desired dissemination and coverage of the target population. However, the corresponding social marketing strategies to create this demand are not yet developed and the acceptance of Golden Rice remains an open question – which nevertheless can be influenced through appropriate measures. In this context the task of an *ex-ante* analysis cannot be to try to second-guess future developments, but to provide information that can help in the design of these very strategies and to support policy makers in their decisions (Qaim and von Braun 1998). In this case an *ex-ante* analysis can use scenarios with different coverage rates to demonstrate possible effects of different strategies.

Potential avenues for the dissemination and promotion of Golden Rice to the target groups are in particular the existing systems in place in India to ensure food security, like the PDS and the Integrated Child Development Services (ICDS). Through the PDS, in so-called "fair price shops", essential commodities are sold at subsidised prices; there is also a "Targeted Public Distribution System" in place, a delivery system that specifically targets the poor (GoI 2005a, GoI 2005b, GoI 2001). Through the ICDS, in community-based childcare centres (anganwadis), children from low-income families and from deprived sections of the society receive supplementary feeding; the anganwadis are also used as contact points to counsel mothers and pregnant women, to provide nutrition education and to distribute targeted supplementation (GoI 2005c).[12] The Ministry of Human Resource Development, supported by the Ministry of Consumer Affairs, Food & Public Distribution, also implemented a mid-day meal scheme that covers children in primary schools, who are supplied with 100 grams of food grains (wheat or rice) per school day (GoI 2005a). Obviously the success of using these channels depends on their effectiveness in fulfilling their purpose, which was doubted by some of the decision makers referred to in the previous section who mentioned corruption that would, especially in the case of the PDS, lead to misuse of the food.

One advantage of using the public systems is that a market for Golden Rice will be created because public authorities generate demand for it; hence farmers will start growing Golden Rice. Because the cultivation of Golden Rice and any share it can gain in overall rice consumption will probably be more *demand-driven*, i.e. both the government's assumed role as a buyer as well as any potential social marketing campaigns that promote Golden Rice will generate demand (and acceptance) and impel farmers to grow Golden Rice. In the case of biofortified crops that do not experience a colour change (like e.g. iron-rich rice) and where consumers might not even distinguish iron-rich and conventional varieties, the approach to increase their coverage is essentially a different one in that it needs to be *supply-driven*: the "micronutrient trait" is added

[12] According to GoI (2005c), the budgetary allocation to the ICDS for the year 1999-2000 was Rs. 8558m, which is about US$ 200m.

to new crop releases that farmers adopt for their other (agronomically advantageous) characteristics. Hence these biofortified crops enter the markets because farmers grow them and not because consumers (or the government) ask for them. Of course this does not mean that the "golden trait" will not also be combined with other, agronomic traits to entice farmers to opt for growing Golden Rice anyway.

An initial demand that is built up if public systems starts sourcing Golden Rice will not only ensure a sales market for Golden Rice, but it might then feed through to the cultivation of rice in general – if more farmers learn of it (and if more consumers ask for it). This potential mechanism may also counteract a weakness of promoting Golden Rice through the public systems, namely that a market demand for Golden Rice will not persuade subsistence farmers to grow it, nor will rural labourers who receive their payment in kind be reached as long as Golden Rice is confined to the PDS. Therefore the agricultural extension system will also have a role to play in the promotion of Golden Rice in rural areas, as will the general health system.

To take account of the considerable uncertainty that surrounds the potential share of Golden Rice in overall rice consumption, we use the following set of assumptions for the low impact and a high impact scenario. In both cases it is assumed that the scenario described will be reached 15 years after the first release of Golden Rice:

- In the <u>low impact</u> scenario 20% of the rice that is distributed through the PDS will be replaced by Golden Rice, the other rice will be replaced by Golden Rice only one day per week (i.e. 14.3% of the other rice will be replaced)[13], 10% of rice products will consist of Golden Rice and in those parts of the country where wheat is not the dominating staple food, the meals in schools, balwadis (child care centres/nursery schools), etc. contain 100g Golden Rice once a week.
- In the <u>high impact</u> scenario 100% of the rice that is distributed through the PDS will be replaced by Golden Rice, the other rice will be replaced by Golden Rice every other day (i.e. 50% of the other rice will be replaced), 50% of rice products will consist of Golden Rice and in those parts of the country where wheat is not the dominating staple food, all meals in schools, balwadis, etc. contain 100g Golden Rice.

4.5 Potential impact of Golden Rice

As was shown in section 2, the current burden of VAD in India is 2.3 million DALYs lost each year. To determine the potential impact of Golden Rice it is necessary to calculate the burden of VAD for a (hypothetical) situation in which people consume Golden Rice; the difference between these two burdens is the impact of Golden Rice.[14] The burden of VAD is expressed in "DALYs lost" and the corresponding DALYs are calculated based on VAD-related incidence and mortality rates. Yet, as was outlined in the previous section, Golden Rice is expected to improve the consumption of VA and, by extension, the VA status of the consumers of Golden Rice. Therefore the challenge is to translate such an improvement of the VA status into a reduction of the associated incidence and mortality rates that enter the DALY calculations. Based on

[13] One day out of seven is 1/7, which translates to 0.143.

[14] Due to lack of data, in our analysis we cannot determine which individuals have received VA supplements or to which extent these supplements could have contributed to ameliorating their VA status. Therefore, our results reflect the efficacy of GR in improving individual VA statuses in a situation in which there is no VA supplementation. Apart from the low coverage rate of the current programme and the poor targeting of such programmes in general (Adamson 2004), which suggests that the distortion of our results is rather small, this is also reasonable in that supplementation is generally considered to be a more targeted and short-term intervention, i.e. with GR the existing VA programme could be reduced in size but become more focused on the remaining cases of VAD. Yet, current prevalence rates are already reduced – to some extent – by VA supplementation. Hence, without supplementation the problem would be bigger, but so would be the impact of GR. Therefore, if anything, our results are underestimates of the true effectiveness of GR.

Zimmermann and Qaim (2004) and Stein et al. (2005a), this can be done by relying on a "dose-response" function: the gap between actual VA intakes and requirements in the *status quo* is compared to the smaller gap between intakes and requirements in the situation where Golden Rice is consumed. The efficacy of closing the gap can be computed. This efficacy, i.e. the relative reduction, can then be applied to the VAD-related incidence and mortality rates, which subsequently enter the new DALY calculations to determine the burden of VAD in a situation where Golden Rice is consumed by the population. If this is done for the two scenarios lined out in the previous sections, Golden Rice can reduce the burden of VAD in India by more than 50 percent, saving 1.4 million healthy life years per year (Table 3). However, in the low impact scenario Golden Rice shows a more minor impact but still saves more than 200,000 DALYs. This result clearly shows how important it is to breed sufficient amounts of bioavailable beta-carotene into the rice and to achieve widespread acceptance and consumption of Golden Rice.

Table 3: The impact of Golden Rice on VAD in India (DALYs and lives lost)

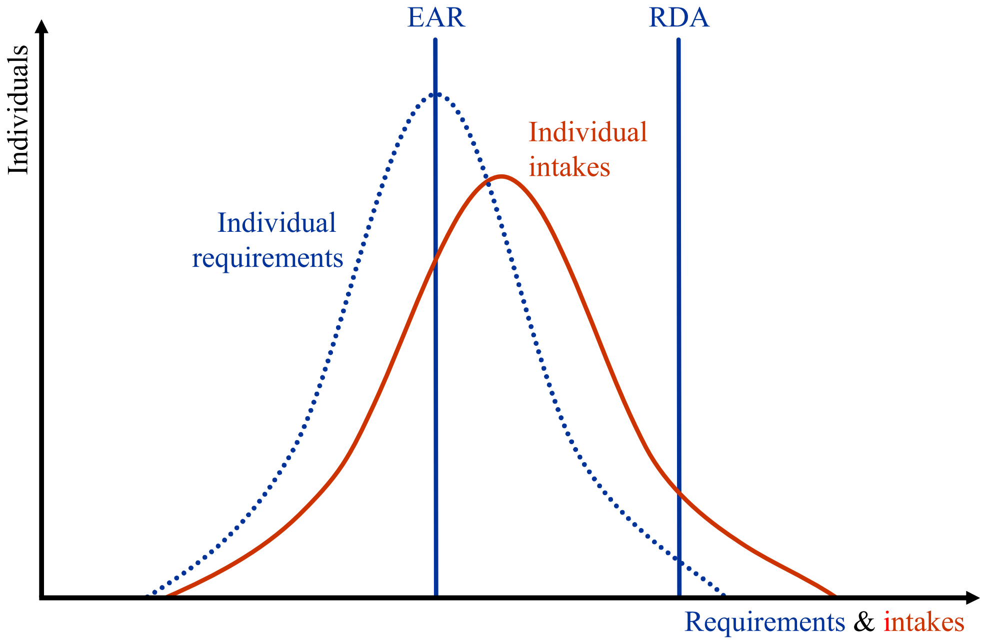
Scenario	Old burden (units lost)	New burden (units lost)	Gain (units)	Reduction
		*DALYs**		
Low impact	2.3m	2.1 million	204,053	-8.8%
High impact		0.9 million	1.4 million	-59.4%
		*Lives**		
Low impact	71,625	66,168	5,457	-7.6%
High impact		31,901	39,725	-55.5%

* One DALY is one healthy life year; future DALYs are discounted at 3 percent. The average age of death due to VAD-related causes is 1 year and the average life expectancy for Indians aged 1-4 years is 64.4 years (WHO 2001a); the life years contained in these 64.4 years are not discounted because the unit is "lives" and not "years". Yet, in terms of DALYs – because of the discounting – one of these lives corresponds to 28.5 DALYs only.

In these calculations it is assumed that the dose-response is not linear, i.e. for the same absolute increase in VA intake a more deficient individual improves her VA status more than a less deficient individual. Furthermore, while both Zimmermann and Qaim (2004) use recommended dietary allowances (RDAs) as cut-off levels to calculate the intake gap, the VA requirements that are used for our calculations are the estimated average requirements (EARs) of the Institute of Medicine (IOM 2002). RDAs ensure sufficiency at an *individual* level by fixing the recommended intake at a level that leaves 97-98 percent of all individuals without risk of suffering from VAD. Such a high threshold would overestimate the intake gap at a *group* level (Figure 3, Barr et al. 2002, Murphy and Poos 2002). Intakes and requirements of VA can expected to be uncorrelated and both are normally distributed. High and low individual requirements are therefore met by low and high individual intakes and partly cancel out (Barr et al. 2002, IOM 2000, especially Fig. 4-8). Therefore we use EARs.

Following a different reasoning Fiedler et al. (2000) use intakes below 70 percent of RDA as a proxy indicator of VAD. The EARs for VA are approximately 70 percent of the respective RDAs, which seems to corroborate the actual size of the cut-off figures we use.

Figure 3: Illustration of requirements and intakes of vitamin A



5 Potential cost-effectiveness of Golden Rice

5.1 The costs for the development and the dissemination of Golden Rice

To establish the cost-effectiveness of Golden Rice, the costs for its development and dissemination need to be taken into account, too. The costs that have to be incurred for R&D and testing until the release of Golden Rice can roughly be divided into five categories: (i) R&D costs that are incurred at the international level, (ii) breeding costs within India, (iii) regulatory costs that need to be incurred prior to the release of Golden Rice, (iv) social marketing costs that need to be incurred to promote and popularise Golden Rice and (v) costs for maintenance breeding. Overall, a time frame of 30 years is considered for analysis.

The initial research costs that were not incurred for the actual development of Golden Rice as an agricultural crop but for more basic, principal research were not included; such costs – covered by governments or private foundations – can be seen as financing proofs of concept. According to Mayer (2005), the beginning of the specific product development can be dated on the year 2001. While some of the work was undertaken by Peter Beyer in Freiburg (Mayer 2005), efforts were continued by researchers of Syngenta in Japan, in the UK and in the USA (Dubock 2005). More R&D was also undertaken at the International Rice Research Institute, which is expected to end in 2007. These international R&D costs were attributed to India according to its share in the total rice production of the three primary target countries; these are India, Bangladesh and the Philippines. China, Indonesia and Vietnam are further target countries that are not considered for the attribution of the costs, though (Barry 2005). Only in the high impact scenario China is included as target country, which halves the international R&D costs that are attributed to India.[15] In India research for Golden Rice started in 2002 at the Indian Agricultural Research Institute in New Delhi and at the Directorate of Rice Research in Hyderabad. In 2005, the actual development of Golden Rice for the Indian market will be started, for which the R&D budget will be increased and some of the work will also be done at the Tamil Nadu Agricultural University (Singh 2005). Apart from these R&D costs, further costs need to be incurred to comply

[15] Based on FAO (2004), if the R&D costs at the international level are only attributed to India, Bangladesh and the Philippines, India's share amounts to 70.5%. If China is included this share sinks to 34.2%. And if the costs were to be divided between all developing countries in Asia, India's share would sink to 23.2%.

with regulatory requirements (Rao 2005). In the low impact scenario the actual costs obtained from the experts involved (breeders and regulators) were increased by 10 percent for past costs, and costs from 2005 onwards were increased by 25 percent to take account of possible omissions, underreporting and future cost increases. In the high impact scenario only future costs were increased by 10 percent. In the low impact scenario the development period was moreover increased by 2 years to accommodate potential delays in the breeding and regulatory process. The aggregated and undiscounted development and regulatory costs considered are given in Table 4.

Once the first varieties of Golden Rice are released to the farmers, which is expected for 2010 in the high impact scenario and for 2012 in the low impact scenario, additional costs are expected to arise for maintenance breeding until the end of the 30 year period considered; these costs are taken from Stein et al. (2005b) and amount to US$ 100,000 per year in the high impact scenario, which are again increased by 25 percent in the low impact scenario. In the first years of the release of Golden Rice, promotion campaigns and social marketing efforts will also be necessary to increase acceptance of the yellow coloured rice. According to expert estimates, a general nation-wide health campaign – including electronic media – is about Rs. 10 million (or rounded US$ 250,000), awareness programmes in the framework of the ICDS cost about Rs. 1,000 per ICDS centre (for 650,000 centres that amounts to Rs. 650 million or rounded US$ 15 million) and smaller campaigns and special programmes in the framework of the ICDS cost about Rs. 65,000 per ICDS unit (for 43 units that amounts to Rs. 2.8 million or rounded US$ 70,000). In the high impact scenario it is assumed that two large-scale awareness programmes and two nation-wide campaigns are carried out in the first and third year of the release of Golden Rice and that smaller campaigns are carried out in the years 2, 4 and 5. In the low impact scenario only one awareness programme is carried out in the year of release and nation-wide campaigns are carried out in the first and third year, while smaller campaigns are carried out in the second year. With these assumptions the aggregated and undiscounted social marketing costs are US$ 30.7 million in the high impact scenario and US$ 15.6 million in the low impact scenario. Here the social marketing costs are actually higher in the high impact scenario, but this is to explain and justify the higher assumed adoption of Golden Rice by the farmers and consumers. Overall, the total present costs of Golden Rice (for development, breeding, regulation, dissemination, marketing and maintenance efforts over 30 years) that are used in this analysis amount to 21.4 million US$ in the low impact scenario and to 27.9 million US$ in the high impact scenario, which corresponds to an average annual cost of US$ 713,000 and US$ 931,000, respectively.

Table 4: Aggregated development and regulatory costs of Golden Rice (million US$)

Scenario	Share of internat. R&D costs	Breeding costs within India	Regulatory costs within India	Total costs
Low impact	7.5	1.2	2.5	11.1
High impact	3.3	0.8	2.2	6.2

Source: Based on Mayer (2005), Dubock (2005), Barry (2005), Singh (2005) and Rao (2005).

5.2 The cost-effectiveness of Golden Rice in comparison

If the potential health gains (Table 3) are incorporated into the 30 year time frame lined out in the previous section and juxtaposed to the related costs for development, maintenance and social marketing, the costs for saving one healthy life year can be as low as US$ 3.06 (Table 5). Because discounting health benefits is sometimes disputed in the literature (c.f. Stein et al. 2005a), we also provide a separate set of results in which future DALYs are not discounted.

Otherwise both future DALYs and costs are discounted consistently at a rate of 3 percent (Stein et al. 2005a). Table 5 also gives the hypothetical costs of Golden Rice per capita of the overall population – and this amount of maximal US$ 0.0009 or about Rs. 0.05 is negligible, even in local terms. At the same time these figures illustrate that the higher overall costs in the high impact scenario, due to higher costs for additional social marketing activities, are overcompensated by the additional DALYs that can be saved if Golden Rice experiences a higher dissemination. Therefore, whether the low impact or the high impact scenario comes true is, to a large extent, in the hands of the policy makers and, quite likely, the media.

Table 5: Costs and cost-effectiveness of Golden Rice in India

Scenario	Cost per DALY saved	Cost per DALY saved w/o discounting of health benefits	Cost per capita
Low impact	US$ 19.40	US$ 4.76	US$ 0.0007
High impact	US$ 3.06	US$ 0.74	US$ 0.0009 [a]

[a] The costs in the high impact scenario are higher than in the low impact scenario because of higher assumed costs for social marketing activities, which justify the higher assumed dissemination of Golden Rice in the high impact scenario.

The DALY approach has first been used by the World Bank in its World Development Report 1993 to classify the cost-effectiveness of public health interventions. Therein the World Bank qualifies all interventions as *highly* cost-effective that cost less than US$ 150 per DALY saved; in real 2005 Dollars this threshold would rise above US$ 200.[16] In another publication the World Bank (1994) gives the figure of US$ 50 per DALY as an upper boundary for most micronutrient programmes; this corresponds to about US$ 65 in current Dollars. The World Health Organisation (WHO 2001b) has classified interventions as *very* cost-effective that cost as much as the gross domestic product (GDP) per capita and those that cost three times GDP were still classified as cost-effective; in India the per capita income is about US$ 500 (World Bank 2004) and, therefore, costs of up to US$ 1,500 could still be defined as cost-effective.[17] A recent analysis of different strategies to improve child health in developing countries reports costs of 237-277 international $/DALY for fortification of sugar with VA and 377-1,686 international $/DALY for biannual VA supplementation, for South-East Asia and depending on the coverage levels achieved (Tan-Torres et al. 2005, online Table B). The authors point out, though, that the cost-effectiveness ratios in their analysis are relatively higher than those in the literature because of the use of international dollars and that the removal of age weighting in the DALYs calculation, which they use, increases the health gains and makes the interventions more cost-effective. Combining different interventions, Tan-Torres et al. (2005) report much lower costs of 35-39 international $/DALY – again depending on the coverage rates achieved – for zinc fortification and VA fortification in South-East Asia. These figures, together with the cost-effectiveness of a hypothetical alternative programme (Box 1), form the basis on which Golden Rice can be assessed.

With per-DALY-costs falling in a range of US$ 3-19, Golden Rice is considerably cheaper than the – very optimistically calculated – alternative intensification of VA supplementation (53-142

[16] To convert the nominal US Dollar values into real terms, the inflation calculator of the US Bureau of Labor Statistics was used, which is based on the average consumer price index (CPI).

[17] If purchasing power would be considered the Indian per capita income – and hence the WHO thresholds for cost-effectiveness – would be even higher: for the year 2000 Heston et al. (2002) give a value of about US$ 2,500 for the Indian GDP. The costs of Golden Rice would not rise as much, though, because a lot of the R&D is carried out at the international level.

US$/DALY). It is also much cheaper per DALY saved than the World Banks threshold for micronutrient programmes (65 US$/DALY) and compared to the general yardsticks of the World Bank and the WHO for the assessment of health interventions (200-1,500 US$/DALY) its per-DALY-costs are almost negligible. Even if allowing for methodological differences (i.e. the use of international dollars and age weighting), Golden Rice is also more cost-effective than VA fortification alone. And while an intervention that combines zinc fortification and VA fortification may be more cost-effective than Golden Rice in the low impact scenario, in our analysis we did not look at the possibility of multiple biofortification of rice. However, next to Golden Rice efforts are under way to fortify rice with both iron and zinc – and it has been shown that both approaches may be very cost-effective (Stein et al. 2005b and forthcoming). Hence Golden Rice certainly qualifies both as a very cost-effective intervention and as an economically sensible complement to the existing efforts to combat VAD. (To assess Golden Rice in India based on purely financial indicators, a cost-benefit analysis is carried out in the appendix.)

Box 1: Deriving a yardstick for the cost-effectiveness of VA interventions in India

To engage in a quick but illustrative calculation: Even though India has a long-standing supplementation programme, not even half of all children below the age of 5 years are reached, which speaks for the problem such large-scale programmes have to cope with. For the sake of our illustrative calculation it is assumed that pharmaceutical supplementation is nevertheless to be used to completely eliminate VAD amongst children below the age of 5 years. The current cost of the VA liquid used is Rs. 2 per 2 ml; children from the age of 1 year onwards are given 2 ml, children aged 6-12 months receive only 1 ml (Kapil 2005). MI's *marginal* cost per VA capsule is 5 US Cents (Laviolette and Bulusu 2005), which also corresponds to Rs. 2. Based on a study in the Philippines, it can be assumed that the cost of the supplement constitutes around 3 percent of the total cost of providing one dose (Fiedler et al. 2000). Consequently each dose provided costs around Rs. 67. Kapil (2005) gives a somewhat lower estimate of Rs. 50 per dose and – in a synthesis of analyses of VA supplementation programmes in three countries – Rassas (2004) gives the average cost of US$ 1.14 per child dosed twice a year. This corresponds to a cost of Rs. 50 per child and of Rs. 25 per dose.

In its annual report 2003-2004, MI (2004) states that in India about 40 million children under 5 years of age are covered by VA supplementation efforts. Following MI and UNICEF, which propose the coverage of all children aged 6-60 months and not only of children aged 6-36 months as the national programme recommends, this leaves 100 million children uncovered. As each child needs two doses per year and using the figures of Rs. 25 and Rs. 67 per dose, the additional cost for reaching full coverage amongst pre-school children in India amounts to Rs. 5.0-13.4 billion, or about US$ 116-312 million, *each year*.*

Assuming an unrealistically optimistic 100 percent effectiveness of the supplementation in the elimination of VAD amongst those who receive it, this leaves only a remaining annual burden of VAD of about 100,000 DALYs lost due to night blindness amongst pregnant and lactating women. Juxtaposing the 2.2 million DALYs saved through this hypothetical supplementation programme and the cost of US$ 116-312 million, each DALY saved comes at a cost of US$ 52.7-141.8 – and this despite the very optimistic assumptions about costs and effectiveness.

* To facilitate the calculation it is assumed that the cost of providing 1 ml to infants is the same as the cost of providing 2 ml to the older children. This may also account for possible spilling and other losses. Although this is a very unrealistic (but conservative) assumption, for these cost estimates it is also assumed that increasing the coverage of the programme does not run into increasing costs – even when coverage is extended to the most remote and difficult to reach areas.

6 Conclusions

In the introduction we had undertaken to look at the *potential* contribution of genetic engineering to the alleviation of malnutrition through the improvement of the nutritional content of staple crops by analysing the impact and the cost-effectiveness of one new tool, Golden Rice. The overarching long-term goal in combating micronutrient malnutrition and in ensuring food security in general certainly needs to be the improvement of people's livelihoods – so they can afford a nutritious, balanced and diverse diet – and to increase their nutritional knowledge and awareness. However, Golden Rice could be used in intermediate strategies of addressing one particular form of micronutrient malnutrition, vitamin A deficiency.

In our analysis we have clearly shown that the genetically modified Golden Rice *can* indeed improve the vitamin A status of a rice-eating population to an extent that it has a considerable impact on this population's burden of VAD: for a given set of optimistic assumptions the current burden of VAD in India of 2.3 million DALYs lost each year could be reduced by more than 50 percent. Given the rapid transfer of the best performing lines of Golden Rice to India, a speedy regulation of this new crop and its wide dissemination and acceptance, saving one healthy life year through Golden Rice could cost as little as US$ 3.06 – or about Rs. 140, which is less than a week's earning of a poorly paid rural day labourer. Yet, given the complex nature of the problem and the complementary characteristics of the different micronutrient interventions, we do not stipulate that Golden Rice is a panacea in the fight against VAD or that genetic engineering is the silver bullet for combating malnutrition in general. It is but one potential intervention.

Nevertheless, while genetically engineered Golden Rice might offer benefits also for the poor and malnourished, this potential is not realised by itself – as is shown for the low impact scenario where Golden Rice still proves to be cost-effective compared to other interventions, but where its overall impact on the burden of VAD is rather small. To bring the potential of Golden Rice to its fruition would require pro-active and targeted implementation of the related R&D and dissemination activities as well as broad public support. Of course, whether Golden Rice is to be used after and when it has safely passed the relevant national regulations, and how it should or could be integrated into the existing mixture of the different and complementary nutrition and health interventions, remains the decision of the respective policy makers. However, their commitment is the more important as it is in their hands to promote the wide-spread acceptance of Golden Rice, which has a decisive influence on the ultimate success of reducing the burden of VAD. Therefore, given that Golden Rice promises to do a lot of good for relatively little money, i.e. compared to other interventions, it is probably worthwhile to consider its employment seriously: limited health budgets are a reality and the money that can be saved through the reduction and re-focussing of the scope of other interventions can then be used for other purposes, for instance for the promotion of dietary diversification, which is the generally accepted long-term objective to fight any kind of micronutrient deficiency, not just VAD. In this case Golden Rice would further contribute to a sustainable and permanent solution of micronutrient malnutrition.

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Appendix 1: A cost-benefit analysis of Golden Rice

In the main body of the study we have shown that Golden Rice can be a cost-effective intervention to combat VAD. However, juggling with DALYs, prevalence rates and beta-carotene levels requires some background knowledge and makes it difficult to compare interventions that use different indicators – either within the field of health and nutrition or in the wider field of human development. For this reason a cost-benefit analysis (CBA) is appended to the paper. A CBA measures both costs and benefits in monetary terms and uses standard financial indicators like internal rates of return (IRR), benefit-cost ratios (BCRs) or net present values (NPVs) to gauge the profitability of an investment. Reporting such indicators allows a more general public to get a quick grasp of the economic potentials involved and to put the intervention into a bigger context. Condensing the information contained in the previous cost-effectiveness analysis into just a couple of indicators comes, of course, at the cost of a loss of information. Transforming DALYs into Dollar-values brings additional problems of its own as it requires attaching a monetary value to a healthy life year. Even if this is only done for above described pragmatic reasons, a certain ethical unease remains.

As noted elsewhere (Stein et al. 2005a), DALYs can be valued at standard values of US$ 500 or US$ 1,000 or they can be valued at the national per capita income. While using standard values facilitates comparison across studies, relying on national per capita income reflects more the economic reality within the country itself. In the case of India the value of US$ 500 per DALY corresponds approximately to the current per capita income in real terms, which is why we do not report a separate set of results for the per capita income. If, however, the per capita income is measured at purchasing power parity, the DALY value rises to US$ 2,500 (c.f. footnote 17). As was already noted in the main body of the study, both future DALYs and costs are discounted at a common rate of 3 percent. Taking these additional assumptions into account the results of a set of CBAs of Golden Rice in India – expressed in the internal rate of return (IRR) and in the benefit-cost ratio (BCR) – is given in Table 6.

Table 6: Cost-benefit analysis of Golden Rice in India

	1 DALY = US$ 500		**1 DALY = US$ 1,000**		**1 DALY = US$ 2,500**	
	IRR	**BCR**	**IRR**	**BCR**	**IRR**	**BCR**
Low impact scenario	29%	26	35%	52	44%	129
High impact scenario	66%	163	77%	327	93%	816

While we have seen in the main body of the text that Golden Rice performs very well when its cost-effectiveness is analysed, also these results of a CBA of Golden Rice indicate that it is a sensible investment, even it the analysis is based on a DALY value of US$ 500 only: for example, a cost-benefit meta-analysis of investment in the CGIAR centres yielded IRRs in the range of 17-35 percent and BCRs in the range of 2-17 for the centres' overall agricultural R&D activities[18] and, in their economic analysis of health sector projects, Adhikari, Gertler and Lagman[19] find in reference to multilateral development banks that IRRs higher than the economic opportunity cost of capital, "commonly 10-12 percent", form the basis for project selection.

[18] Raitzer, D.A. (2003). Benefit-cost meta-analysis of investment in the international agricultural research centres. Consultative Group on International Agricultural Research, Food and Agriculture Organisation, Rome.

[19] Adhikari, R., P. Gertler and A. Lagman (1999). Economic analysis of health sector projects:. Economic Staff Paper No. 58, Asian Development Bank, Manila.

Hence, Golden Rice outperforms common returns of agricultural projects and qualifies as sensible health project.

Finally, the present monetary costs and benefits of the investment in Golden Rice over the 30 year time frame considered are reported in Table 7 to show both the potential social returns and the magnitudes of the investment in terms of monetary requirements. Apart from the hypothetical annual costs of an extension of India's VA supplementation programme of US$ 116-312 million (Box 1), the average annual costs of Golden Rice of less than US$ 1 million in either scenario compare, for instance, with the US$ 2.2 million worth of the 23.4 million (different) supplements that the organisation "Vitamin Angel Alliance" has actually shipped to developing countries in the year 2004.[20] But India has about 150 million children under the age of 6 years and, to prevent VAD, two supplements are needed per child per year.

Table 7: Present costs and benefits of Golden Rice in India (US$)

	Low impact scenario	High impact scenario
Present costs in base year	21 million	28 million
Average annual costs (over 30 years)	713,000	931,000
1 DALY = 500 US$		
Present benefits in base year	508 million	4,505 million
Net present value	530 million	4,533 million
1 DALY = 1,000 US$		
Present benefits in base year	1,060 million	9,067 million
Net present value	1,081 million	9,094 million
1 DALY = 2,500 US$		
Present benefits in base year	2,713 million	22,750 million
Net present value	2,735 million	22,778 million

[20] Vitamin Angel Alliance, Santa Barbara, CA. http://www.vitaminangels.com/ourwork.html

Appendix 2: An examination of Shiva's "The 'Golden Rice' hoax"

As Shiva (2000) is frequently used, even if implicitly, as basis for arguments against Golden Rice (also see footnote 2, Greenpeace 2001a-2005 and MASIPAG 2001), her arguments warrant some scrutiny in a study that comes to a rather positive evaluation of Golden Rice.

A notable first impression of her report, which is only available online, is the frequent absence of proper references to support her more specific claims and numbers. This is dissatisfactory, as it makes it difficult to double-check the information she provides and opens the floor for inconsistencies. (For instance she writes "it is not even known how much vitamin A the genetically engineered rice will produce" but yet she affirms confidently that "it will be totally ineffective in removing VAD.")

In her report Shiva bases her argument on a "daily average requirement" of 750 µg of VA, which she seems to suggest would need to be fulfilled to 100 percent through the consumption of Golden Rice alone for the technology to be considered effective. This all-or-nothing definition of effectiveness seems to imply that there is no difference between, say, an individual achieving 50 percent of her requirements and an individual achieving 99.9 percent of her requirements through the current diet: for both individuals, current intakes are not sufficient to prevent VAD. One consequence of this implicit definition of effectiveness is the statement that one has to eat more than 2 kg of Golden Rice, which is clearly misleading. And, indeed, our more detailed analysis has shown that based on current consumption patterns and quantities, Golden Rice can already have a substantial and beneficial impact if it replaces the conventional rice in every other meal.

After introducing the term of "daily average requirement" Shiva uses the acronym "RDA" without prior definition further down in the paragraph. RDA commonly stands for "recommended dietary allowance". Yet, it is unclear whether this is the same as a "daily average requirement". There are "*estimated* average requirements" or EARs, though. According to IOM (2000, p. 3) an EAR is "the average daily nutrient intake level estimated to meet the requirement of half the healthy individuals in a particular life stage and gender group", while an RDA is "the average daily nutrient intake level sufficient to meet the nutrient requirement of nearly all (97 to 98 percent) healthy individuals in a particular life stage and gender group." These definitions show that it is important to differentiate between these concepts, because "RDAs have been established as a target or goal for intake by an individual, and it can be assumed that individuals whose usual intakes are above the RDA are likely to be meeting their individual requirements and thus have adequate intakes. However, the converse is not true. For this reason the RDA is not a useful reference standard for assessing an individual's intake" (p. 51); "the best estimate for an individual's unobservable requirement is the EAR" (p. 50).

To corroborate Shivas "daily average requirement" of 750 µg, for which she has neither given a reference nor a target group to which the requirement is applicable, we compare this figure with a list of different requirements: Gopalan et al. (1989) give India-specific RDAs of 600 µg VA for men, women and children above the age of 6 years, 400 µg for children aged 1-6 years and 350 µg for infants below the age of 1 year. IOM (2002) gives more detailed RDAs of, for example, 900 µg retinol activity equivalents (RAEs) for men, 700 µg for women, 400 µg for children aged 4-6 years and 300 µg for children aged 1-3 years. IOM (2002) also gives EARs of 625 µg RAEs for men, 500 µg for women, 275 µg for children aged 4-6 years and 210 µg for children aged 1-3 years. (For brevity not all groups are reported here.) While it is unclear on which of these concepts Shiva based her figure of 750 µg (probably on a RDA for men), the above quoted, published figures of different sets of requirements are generally smaller – and hence easier to fulfil. Therefore, by deliberately setting a very high requirement, it is easier for Shiva to suggest that Golden Rice would be ineffective.

Having stated her understanding of effectiveness and declared Golden Rice to be totally ineffective in removing VAD, Shiva writes that "besides creating vitamin A deficiency, vitamin A rice will also create deficiency in other micronutrients and nutrients." The rationale for this statement remains unclear, though. Even if Golden Rice fails to improve the VA status of its consumers, being ineffective in reducing VAD is different from creating either VAD or other deficiencies. Ineffective Golden Rice would simply maintain the *status quo*.[21] However, if in the *status quo* the consumption of rice is responsible for VAD, then rice could be used as starting point to combat it. This rationale was followed in the development of Golden Rice.

One valid point in Shiva (2000) is that "raw milled rice has a low content of fat" and that "fat is necessary for vitamin A uptake". However, for the necessary bioavailability of VA only 5-10 g of fat need to be consumed in the food mix (c.f. Stein et al. 2005a). Moreover, Shiva proposes the "propagation of naturally vitamin A rich plants[22] in agriculture and diets" and she provides a list of "sources rich in vitamin A used commonly in Indian foods" (Table 8). As before she has suggested that the low fat content in rice (she gives the figure of 0.5 g/100g) "will aggravate vitamin A deficiency", one could probably expect that the fat content in these food items is much higher, so their consumption can alleviate VAD. Yet, the fat content in the plant foods Shiva proposes is on average 0.5 g/100g (with a range of 0.1-1.7 g/100g, (Table 8) just like the fat content in rice. Therefore, following this logic, these foods also aggravate VAD. Otherwise, if fat is not a limiting factor, both these plants and Golden Rice could and should help in fighting VAD.

Another open question with her list of foods is the "content" she reports for them: in plant food there is no VA, i.e. for all the plant foods she enlists as being VA-rich she must have derived the VA content from the respective beta-carotene contents. Yet, she does not provide a reference neither for the conversion rates used nor for the source of the original data on the beta-carotene and VA contents of the food items. We therefore used published data on food composition and conversion (Gopalan et al. 1989, USDA 2004, Erhardt 2005) to derive the VA content of the food items she mentioned. To be sympathetic to her arguments, we used the highest VA content[23] for each food item where there was different information in the three sources we used (Table 8). Following her own reasoning in judging Golden Rice, which is based on how much of it would need to be consumed to achieve a requirement of 750 μg, we also report how much of each of the food items she proposed would need to be consumed per day to achieve a requirement of 750 μg (Table 8). It turns out that people would need to eat as much as 8 kg cabbage, 5 kg jackfruit, 1.8 kg tomatoes, 0.8 kg oranges or 4 eggs per day to meet their supposed full daily needs. And while it might be possible to eat 328 g mango (i.e. approximately 1.5 fruits), the question of affordability and seasonality remains. So it becomes obvious that Shiva probably did not want to suggest that one food item alone should cover 100 percent of VA requirements, but rather that any food rich in VA or beta-carotene should contribute to the fulfilment of requirements. This is what Golden Rice is expected to do as well, as the analysis in the main body of this study – which has used actual consumption data of rice – has shown. Because, contrary to rice, the "sources rich in vitamin A used commonly in Indian foods" that

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[21] For instance, Potrykus (2005, p. 27/28) shows that the genome of the popular conventional rice variety IR64 is less different from "golden" IR64 than from other rice varieties and that it only differs from "golden" IR64 in one recombination. Hence, even if Golden Rice would fail to improve the VA status of at-risk populations it is unclear how it should create VAD or other deficiencies on top of those associated with the normal consumption of rice (Potrykus, I. (2005). Golden Rice, vitamin A and blindness. Presentation at the Swiss Federal Institute of Technology, Zürich, March 18. http://www.goldenrice.org/PDFs/Potrykus_Zurich_2005.pdf).

[22] Plants do not contain VA directly, only food from animal sources does. Plants produce carotenoids that the human body can convert into VA (it is these carotenoids that give Golden Rice its golden hue). So Shiva probably means plants that are naturally rich in beta-carotene.

[23] For plant foods the VA content is a theoretical figure that is derived from the plants' beta-carotene content using appropirate conversion factors (USDA 2004, Erhardt 2005).

Shiva mentions do not seem to be that common after all. Otherwise VAD would be less of a problem: Perhaps these plants are only seasonally available, or people do not have the purchasing power to afford the food items she mentioned, or they lack the awareness of their nutritive value, or they simply do not like them (i.e. they do not belong to their dietary habits). Therefore, and as our study has shown, until purchasing power has risen amongst the poorest strata of Indian society, until nutrition education and behaviour change efforts have induced a higher consumption of such VA-rich foods, Golden Rice can have an intermediate role to play in combating VAD.

Table 8: Shiva's selection of Indian foods and their VA and fat contents

Taken from Shiva (2000)		Based on Gopalan et al. (1989), USDA (2004) and Erhardt (2005)		
Source	**"Content" (µg/100g)**	**VA content (µg/100g)[a]**	**Grams to reach 750 µg VA**	**Fat content (g/100g)**
Cabbage	217	9	8,333	0.1
Jackfruit	54	15	5,000	0.1
Tomato, ripe	32	42	1,786	0.2
Orange	35	92	815	0.2
Radish leaves	750	221	339	0.4
Mint	300	228	329	0.6
Mango, ripe	500	229	328	0.4
Curry leaves	1,333	315	238	1.0
Coriander leaves	1,166 - 1,333	337	223	0.6
Amaranth leaves	266 - 1,166	348	216	0.5
Pumpkin, yellow	100 - 120	369	203	0.1
Fenugreek leaves	450	379	198	0.9
Spinach	600	469	160	0.7
Carrot	217 - 434	602	125	0.2
Drumstick leaves	1,283	820	91	1.7
Milk, buffalo	50 - 60	53	1,415	4.1
Milk, cow		64	1,172	6.5
Egg, hen	300 - 400	420	179	13.3
Butter	720 - 1,200	960	78	81.0
Liver, sheep	6,600 - 10,000	6.690	11	7.5
Liver, goat		7.391	10	3.0
Cod liver oil	10,000 - 100,000	30.000	3	99.8

[a] For data from Gopalan et al. (1989) the VA content was obtained using the conversion factors of Erhardt (2005) to derive VA content from the original information on beta-carotene content.

One more question about Shiva's list of VA-rich Indian foods is the inclusion of cod liver oil. While cod liver oil certainly is extremely rich in VA, it is not "food" that is commonly eaten in India – it is also notably absent in Gopalan et al.'s book on the "Nutritive value of Indian foods" (1989). Cod liver oil is rather a medicine and, therefore, promoting the consumption of, perhaps, one tablespoon cod liver oil per week resembles more supplementation than a food-based intervention. And the cost as well as, to some extent, the relative failure of VA supplementation in sustainably alleviating VAD were the very reasons for the development of Golden Rice in the first place.

On the face of it, Shiva's criticism of Golden Rice seems to build on soft ground and a more rigorous analysis would have been desirable. Yet, the actual reason for this criticism becomes clear in the last part of her report where she criticises input-intensive industrial agriculture, an oligopolistic and powerful biotech industry and its aspiration to exclusive ownership of intellectual property rights (IPRs) related to rice research, and the assimilation of public sector research with corporate interests. It is in this context that Shiva considers Golden Rice to be a Trojan horse of big biotech and seed companies to establish corporate control over rice production and to increase the acceptability of GM crops in general. Any economist probably agrees that oligopolistic tendencies and unequal market powers should be corrected as they induce market failures and lead to inefficiencies. The issue of IPRs and the patenting of plants, especially in the context of developing country agriculture, is also an acknowledged problem.[24] Unease about undue influence of agricultural businesses in politics and on regulators is understandable, too.[25] And the need to counter-balance biotech-related R&D efforts in and for the private sector in industrialised countries with the promotion of research for farmers and food consumers in developing countries has also been stated.[26] Therefore, some of the underlying arguments in Shiva (2000) against the current situation and the developments in the agricultural sector merit attention and probably even intervention, indeed, but the debate about the introduction of Golden Rice and its potential to address VAD should not be absorbed by the much more fundamental one about which agricultural system should be preferred. In the current system, if and when it is regulated and approved by the respective national authorities, Golden Rice promises to do a lot of good compared to the *status quo*.[27] Therefore, Golden Rice should be considered seriously by policy makers who have to decide about ways to combat VAD. This does not prevent any proponent of a different approach to agriculture, like Shiva, from arguing that doing agriculture differently in principle could also address problems in the related field of nutrition.

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[24] For example see Timmer (2003).

[25] For example see Newell, P. and D. Glover (2003). Business and biotechnology: regulation and the politics of influence. IDS Working Paper No. 192. Institute of Development Studies, Brighton; Beckwith, J.A., T. Hadlock and H. Suffron (2002). Public perceptions of plant biotechnology and genetically modified foods. Research Report No. 578. Michigan State University, East Lansing, MI.; Williams, T. (2001). The corruption of American agriculture. Americans for Democratic Action Education Fund, Washington, DC.

[26] For example see Qaim (2001).

[27] Interestingly enough, as has already been mentioned in the main body of this study (section 3.7), in the *status quo* the main intervention to combat VAD is pharmaceutical supplementation. The concomitant dependency on and the influence of big international chemicals companies is probably not to the liking of many opponents of Golden Rice either.

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